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March 25, 2016

VIA ECF

Honorable Irene M. Keeley
United States District Court
Northern District of West Virginia
500 West Pike Street
Clarksburg, WV 26301

Re: *Takeda GmbH, et al. v. Mylan Pharmaceuticals Inc.*
Case No. 1:15-cv-00093
US District Court for the Northern District of West Virginia

Dear Judge Keeley:

Mylan Pharmaceuticals Inc. ("Mylan") submits this letter pursuant to this Court's December 1, 2015 order staying the matter and requiring the parties to inform the Court of any developments regarding Mylan's interlocutory appeals in *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, No. 2015-1456, and *AstraZeneca AB v. Mylan Pharmaceuticals Inc.*, No. 2015-1460. In Mylan's view, the Federal Circuit's March 18, 2015 decision should have no immediate impact on Mylan's pending motion to dismiss for lack of personal jurisdiction in New Jersey. Mylan plans to seek panel and en banc rehearing in the Federal Circuit.

The Federal Circuit's *Acorda* and *AstraZeneca* decision suffers several fatal flaws that make it a strong candidate for further review. Most fundamentally, the upshot of the *Acorda* and *AstraZeneca* decision is that submission of an Abbreviated New Drug Application ("ANDA") filing to the FDA gives rise to specific personal jurisdiction in any suit related to that filing in every jurisdiction in the Nation. *See, e.g.*, Brenda Sandburg, *Have Patent Will Travel: Brand Firms Can File Infringement Suits Anywhere*, Pink Sheet Daily (Mar. 18, 2016). The notion that there can be specific jurisdiction everywhere based on the act of filing an ANDA in Maryland is contrary to the basic notion of specific jurisdiction and the more basic constitutional guarantees at the heart of the Supreme Court's due process/personal jurisdiction jurisprudence. *See, e.g. Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945); *Milliken v. Meyer*, 311 U.S. 457, 463 (1940).

Equally important, the panel decision creates an ANDA-specific end run around the Supreme Court's decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014). Before *Daimler*, personal jurisdiction in ANDA infringement cases was typically rooted in general personal jurisdiction doctrine and generic drug manufacturers were vulnerable to suit in jurisdictions across the country under the then-prevailing law. *Daimler* radically altered—and substantially

narrowed—the scope of general jurisdiction, but the Federal Circuit's decision simply recreates the pre-*Daimler* status quo by allowing courts throughout the nation to rely on specific personal jurisdiction where general jurisdiction is no longer available.

The *Acorda* and *AstraZeneca* decision is also in direct conflict with at least two additional independent strands of personal jurisdiction precedent. First, the Federal Circuit wrongly looked past Mylan's current contacts with Delaware to contacts that the company might one day have with the forum should its ANDA be approved. The Supreme Court's recent decision in *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014), makes plain that the only "jurisdictionally relevant" suit-related contacts for purposes of specific personal jurisdiction analysis are those that a defendant has already formed when the suit is filed. "[P]ersonal jurisdiction cannot be based on future contacts, even if such contacts are allegedly inevitable." *Eli Lilly & Co. v. Nang Kuang Pharm. Co.*, No. 1:14-cv-01647, 2015 WL 3744557, at *1 (S.D. Ind. June 15, 2015); *see Fastpath, Inc. v. Arbela Techs. Corp.*, 760 F.3d 816, 822 (8th Cir. 2014) (potential "future development" "is not relevant in" personal jurisdiction analysis). The Federal Circuit's decision disregards this bedrock principle.

Second, the *Acorda* and *AstraZeneca* decision renders the Federal Circuit's decision in *Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829 (Fed. Cir. 1999), a dead letter. In *Zeneca*, the Federal Circuit held that submission of an ANDA to the FDA in Maryland did not authorize the exercise of jurisdiction over the ANDA filer by Maryland's federal courts. If the *Acorda* and *AstraZeneca* decision is correct, then *Zeneca* was merely academic. While the act of submitting an ANDA did not itself authorize the exercise of jurisdiction, the potential consequences of that filing authorized the exercise of jurisdiction over ANDA-related disputes in Maryland (and everywhere else).

Mylan's petition for panel and en banc rehearing is due April 18, 2016. Mylan will advise the Court of the outcome of that petition.

With thanks for the Court's attention, I remain

Very truly yours,

/s/ Gordon H. Copland

Gordon H. Copland

GHC/sg
Enclosures
cc: Counsel of record (via ECF)